

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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MICHELLE MADDEN, as Parent and	:	CIVIL ACTION
Natural Guardian and Administrator of the	:	
Estate of MYKENZIE MADDEN, a minor,	:	NO. 05-787
deceased,	:	

Plaintiff,

v.

THE A.I. DUPONT HOSPITAL FOR  
CHILDREN OF THE NEMOURS  
FOUNDATION and CHRISTIAN  
PIZARRO, M.D.,

Defendants.

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EDWARD and SARAH PAPACODA, as	:	CIVIL ACTION
Administrators of the Estate of KAITLYN	:	
PAPACODA, a minor, deceased,	:	NO. 05-3003

Plaintiffs,

v.

THE A.I. DUPONT HOSPITAL FOR  
CHILDREN OF THE NEMOURS  
FOUNDATION and WILLIAM I.  
NORWOOD, M.D.,

Defendants.

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**MEMORANDUM ON DEFENDANTS' DAUBERT  
AND SUMMARY JUDGMENT MOTIONS**

**Baylson, J.**

**January 27, 2010**

**I. Introduction**

Presently before the Court are two medical malpractice cases stemming out of open-heart surgeries performed on young infants who subsequently passed away. Plaintiff Michelle Madden (“Madden”), as parent, natural guardian, and administrator of the estate of the deceased Mykenzie Madden (“Mykenzie”), brings wrongful death and negligence (Counts III and IX), and

lack of informed consent (Count VI) claims against Defendant Christian Pizarro, M.D. (“Dr. Pizarro”). Plaintiffs Edward and Sarah Papacoda (“the Papacodas,” collectively with Madden, “Plaintiffs”), as parents and administrators of the estate of the deceased Kaitlyn Papacoda (“Kaitlyn”), bring medical negligence and lack of informed consent claims against Defendant William I. Norwood (“Dr. Norwood”) (collectively with Dr. Pizarro, “Defendants”).<sup>1</sup>

In both cases, Defendants have filed Motions to Preclude Evidence and Testimony Based upon Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993), Rule 702 of the Federal Rules of Evidence, and for Summary Judgment (Madden, Docket No. 81; Papacoda, Docket No. 83) (hereinafter Daubert Reliability & Fit Mots.), Motions to Preclude Plaintiffs’ Expert Witness, Joseph J. Amato, M.D. (Madden, Docket No. 83; Papacoda, Docket No. 84) (hereinafter Daubert Qualification Mots.), and Motions for Partial Summary Judgment on Plaintiffs’ Informed Consent Claim (Madden, Docket No. 80; Papacoda, Docket No. 82) (hereinafter Partial Summ. J. Mots.). In sum, Defendants seek to preclude Plaintiffs’ expert, Joseph J. Amato, M.D. (“Dr. Amato”), from testifying at trial, and to dismiss all remaining claims. For the reasons that follow, both sets of motions will be denied.

## **II. Factual and Procedural Background**

The Court detailed the relevant factual background for the Madden case in its prior December 24, 2009 Memorandum granting then-named Defendant William I. Norwood, M.D., Ph. D.’s Motion for Summary Judgment by dismissing all claims against him. See Madden v. The A.I. DuPont Hosp. for Children of the Nemours Found., No. 05-787, 2009 WL 5171732, at

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<sup>1</sup>Note that the parties in both cases stipulated to dismiss the A.I. DuPont Hospital for the Children of the Nemours Foundation as a Defendant. (Madden, Docket No. 117; Papacoda, Docket No. 112.)

\*1 (E.D. Pa. Dec. 24, 2009).

In the Papacoda case, taking the Papacodas' allegations as true, the relevant facts are set forth as follows: Kaitlyn, the Papacodas' daughter, was diagnosed prenatally with Hypoplastic Left Heart Syndrome (HLHS), and was born on March 12, 2003. (Compl. ¶ 14.) Mrs. Papacoda, a Connecticut resident, brought Kaitlyn to Delaware to have her treated by Dr. Norwood at the DuPont Hospital and undergo a three-stage open-heart surgical procedure. (Compl. ¶¶ 3, 14.) Dr. Norwood performed the "Norwood Procedure" and the "hemi-Fontan," the first two stages of the surgery, on February 26, 2003, and June 25, 2003, respectively. (Compl. ¶¶ 17, 21.) On August 12, 2003. (Compl. ¶ 3.)

The Papacodas allege that Dr. Norwood, "employed a 'cooling strategy' on cardiopulmonary bypass and for circulatory arrest which was below the standard of care," and was well aware that this strategy was "dangerous and did not offer adequate protection to the brain and other organs of the body," resulting in Kaitlyn's "preventable death." (Compl. ¶¶ 124, 126.) The Papacodas further allege that they were never informed of the "great" "risk of brain injury and organ damage" the surgical procedures posed, the "varying success rates of . . . alternative procedures," and the "experimental" nature of the procedures employed. (Compl. ¶¶ 147-49.) According to the Papacodas, had they been properly informed, they "would not have consented to the surgery and would have had Kaitlyn transferred to another facility." (Compl. ¶ 152.)

Discovery has been completed in both cases. In each, Plaintiffs have identified Dr. Amato as a medical expert to testify as to Defendants' alleged negligence. On October 21, 2009, Defendants filed the pending Motions to preclude Dr. Amato's testimony at trial, and for

summary judgment relief. On December 17, 2009, the Court heard oral argument on these Motions.

### **III. Jurisdiction and Choice of Law**

#### **A. Jurisdiction**

This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a), since the parties are citizens of different states and the amount in controversy exceeds \$75,000. Venue is appropriate under 28 U.S.C. § 1391(a).

#### **B. Choice of Law**

When a federal district court presides over a case grounded in diversity jurisdiction, the court “must apply the choice-of-law rules of the forum state.” LeJeune v. Bliss-Salem, Inc., 85 F.3d 1069, 1071 (3d Cir.1996) (citing Klaxon v. Stentor Elec. Mfg., 313 U.S. 487, 496 (1941)). Delaware law applies here and the parties do not dispute which forum state’s law applies. (Compl. ¶¶ 114, 199; Def.’s Mot. for Summ J. 5-6.) Accordingly, this Court will apply Delaware law to Plaintiffs’ claims in both cases.

### **IV. Daubert Motions**

#### **A. Legal Standard**

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which provides as follows:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliability to the facts of the case.

Fed. R. Evid. 702. The Third Circuit has clarified that Rule 702 has “three major requirements”:

the proffered witness must (1) “be an expert, i.e. must be qualified”; (2) “testify about matters requiring scientific, technical[,] or specialized knowledge”; and (3) present testimony that “assist[s] the trier of fact.” Pineda v. Ford Motor Co., 520 F.3d 237, 244 (3d Cir. 2008). In short, in order to be admitted, an expert’s testimony must demonstrate “qualification, reliability, and fit.” Schneider ex. Rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003.) In addition, Delaware law provides that “[n]o person shall be competent to give expert medical testimony as to applicable standards of skill and care unless such person is familiar with the degree of skill ordinarily employed in the field of medicine on which he or she will testify.” 18 Del. § 6854.

## **B. Discussion**

Defendants’ Motions to Preclude Plaintiffs’ Expert Witness, Joseph J. Amato, M.D., focus on the first Rule 702 requirement of qualification, and their Motions to Preclude Evidence and Testimony Based upon Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993), Rule 702 of the Federal Rules of Evidence, and for Summary Judgment, focus on the remaining requirements. (See Oral Arg. Tr. 25:19-26:10, Dec. 17, 2009, Madden Docket No. 106, Papacoda Docket No. 104.) The Court will address each in turn.

### **1. The Parties’ Contentions**

#### **a. Expert Qualifications**

Defendants aver that Dr. Amato, who is retired and stopped performing surgeries in 2001 or 2002, a year or two before the surgeries at issue in the present cases, is not qualified to testify as an expert at trial. (Madden Qualifications Mot. 2, 7; Papacoda Qualifications Mot. 2, 6.) In particular, Defendants contend that Dr. Amato lacks sufficient familiarity with the hemi-Fontan

procedure using circulatory arrest, because he has no experience with the allegedly problematic cooling techniques used in Kaitlyn and Mykenzie's surgeries, only performed at most four hemi-Fontans out of the 4,000 surgeries he has performed, and was uncertain as to the details of such surgeries or of his history of operations. (Madden Qualifications Mot. 3-6; Papacoda Qualifications Mot. 2-4). Defendants also aver that "Dr. Amato's opinions vacillate concerning the cooling technique" at issue, which is "the very subject of his opinions." (Madden Qualifications Mot. 6; Papacoda Qualifications Mot. 4-5.) Defendants argue that these considerations demonstrate that Dr. Amato lacks the "level of competency" required under Delaware law. (Madden Qualifications Mot. 7; Papacoda Qualifications Mot. 6.) According to Defendants, case law provides that both insufficient clinical experience for the procedure at issue or mere reliance upon medical literature constitute sufficient grounds for finding an expert to be unqualified. (Madden Qualifications Mot. 7-13; Papacoda Qualifications Mot. 7-12.) In addition, Defendants contend that Dr. Amato's opinions as to Kaitlyn's surgeries are based upon unsupported assumptions, because his deposition testimony indicates that he was not familiar with the facts in the record and that he relied upon facts in another case. (Madden Qualifications Mot. 14-19; Papacoda Qualifications Mot. 12-16.) Defendants argue that allowing Dr. Amato to mention this other case would "unfairly prejudice the jury" by alerting them that there is "another case pending before Dr. Norwood." (Madden Qualifications Mot. 19; Papacoda Qualifications Mot. 16.) Defendants thereby conclude that Dr. Amato is not qualified to testify at trial.

Plaintiffs respond that Dr. Amato is an "exceedingly qualified physician, specializing in pediatric cardiothoracic surgery," who "is more than qualified to testify as he is licensed and remains up to date with literature and continues to teach." (Resp. to Madden Qualifications Mot.

3-4; Resp. to Papacoda Qualifications Mot. 3-4.) Plaintiffs contend that “any alleged gaps or deficiencies” in Dr. Amato’s qualification are “factors to be considered by the jury with respect to the weight of the evidence, . . . not grounds to disqualify” him. (Resp. to Madden Qualifications Mot. 5; Resp. to Papacoda Qualifications Mot. 5.) Moreover, Plaintiffs contend that under Defendants’ expert qualifications standard, Defendants’ “own expert is less qualified to testify than Dr. Amato,” because that expert has never performed a hemi-Fontan. (Resp. to Madden Qualifications Mot. 6; Resp. to Papacoda Qualifications Mot. 6.) Plaintiffs then argue that Defendants “completely misrepresent the record” by focusing on his “simple inability” at his depositions to recall certain details about Kaitlyn and Mykenzie’s medical records, an error purportedly committed by Defendants’ own expert. (Resp. to Madden Qualifications Mot. 8; Resp. to Papacoda Qualifications Mot. 8.) Thus, Plaintiffs urge the Court to deny the pending Motions.

**b. Reliability and Fit**

In addition to challenging Dr. Amato’s qualifications, Defendants contend that Dr. Amato’s opinions as to Dr. Norwood’s deviation from the standard of care in treating Kaitlyn and causation of her death are “unreliable and unsupported,” “not based on scientific evidence or methodology,” and “not helpful as they do not fit within the facts of this case.” (Madden Reliability & Fit Mem. 4; Papacoda Reliability & Fit Mem. 4.) In particular, Defendants fault Dr. Amato for ignoring other factors, namely Kaitlyn’s “dysfunctional AV valve,” Mykenzie’s “highly restrictive or intact atrial septum,” and Kaitlyn’s post-surgical complications of acute intussuseption and thrombosis, that may have contributed to or caused death. (Madden Reliability & Fit Mem. 4, 10; Papacoda Reliability & Fit Mem. 8, 11.) Defendants further assert

that Dr. Amato is “unable to articulate the standard of care for the conduct he criticizes,” having inconsistencies in his report and deposition testimony, and provided “no scientific evidence to support [his] opinions” on how Dr. Norwood’s use of purportedly improper cooling and circulatory arrest periods caused Kaitlyn and Mykenzie’s deaths. (Madden Reliability & Fit Mem. 5; Papacoda Reliability & Fit Mem. 5, 15-19.) Defendants contend that this case is similar to numerous past medical negligence cases in which expert testimony was precluded on the basis of unreliability or lack of fit to the particular facts of the case at hand. (Madden Reliability & Fit Mem. 12-16; Papacoda Reliability & Fit Mem. 13-15.) Defendants thereby conclude that Dr. Amato should not be permitted to testify at trial.

Plaintiffs respond that Defendants have misstated the Daubert standard as well as “the record with regard to Dr. Amato’s opinions.” (Resp. to Madden Reliability & Fit Mem. 2; Resp. to Papacoda Reliability & Fit Mem. 2.) Plaintiffs aver that as Defendants’ own expert, Dr. Bailey conceded at his deposition, there is no “spot-on source from the medical literature to support an expert’s every opinion.” (Resp. to Madden Reliability & Fit Mem. 3; Resp. to Papacoda Reliability & Fit Mem. 2.) Plaintiffs further contend that case law has clarified as much by not requiring experts to rely upon published studies in order to provide causation testimony (Resp. to Madden Reliability & Fit Mem. 16-17; Resp. to Papacoda Reliability & Fit Mem. 11-12); Plaintiffs, however, assert that Dr. Amato provided medical literature supporting his opinions, including a medical text stating that “proper cooling is crucial prior to circulatory arrest because in short, the cooler the infant, the slower the rate of metabolic activity, and the lower the potential for organ and tissue damage.” (Resp. to Madden Reliability & Fit Mem. 26; Resp. to Papacoda Reliability & Fit Mem. 19-20.) Plaintiffs aver that the disparity between the



conclusions of Dr. Norwood and Dr. Bailey, and those of Dr. Amato merely show that “opposing experts offer opposing expert views,” which is “certainly no basis for Daubert preclusion.” (Resp. to Madden Reliability & Fit Mem. 24; Resp. to Papacoda Reliability & Fit Mem. 10.) Although Defendants purportedly attempt to “pluck[] isolated portions” from Dr. Amato’s testimony for which he cannot “cite specific medical literature,” Defendants’ expert Dr. Bailey also made several unsupported assertions which Plaintiffs contend present disputed issues that are best resolved by a jury. (Resp. to Madden Reliability & Fit Mem. 17; Resp. to Papacoda Reliability & Fit Mem. 12, 17-18.) Plaintiffs thereby conclude that Dr. Amato’s testimony is reliable and fit to the facts of the present cases.

## **2. Analysis**

### **a. Qualification**

Qualification “requires that the witness possess specialized expertise.” Pineda, 520 F.3d at 243. The Third Circuit has “interpreted [this] requirement liberally” so that “a broad range of knowledge, skills, and training” suffice to qualify an expert. Id. at 244 (internal quotation marks omitted). There is no question that Dr. Amato, who has been trained to be, and has been employed for many years as, a cardiac surgeon has sufficient formal qualifications. He received a Bachelor of Science from Chicago’s Loyola University, a Doctor of Medicine (M.D.) degree from the Loyola Stritch School of Medicine, has been board certified in both Surgery and Thoracic Surgery, is licensed in Illinois, Massachusetts, Maryland, New Jersey, and New York, and has performed both general surgical and cardiovascular thoracic surgical residencies, and a fellowship in surgical research. (Amato Curriculum Vitae (hereinafter Amato C.V.), Resp. to Papacoda Qualifications Mot., Ex. F-1, at 1.) He has had many clinical appointments including

Chief of Rush-Presbyterian St. Luke's Medical Center's ("Rush-Presbyterian") Pediatric Cardiothoracic Surgery Section from 1995 to 2002, a program that he established, and he has been a professor of surgery for three decades, and a professor in Rush-Presbyterian's Department of Cardiovascular-Thoracic Surgery since 1995. (Amato C.V. 2-3.) In addition to receiving numerous awards and inventing several devices useful to his field, Dr. Amato sat on numerous committees respecting cardiothoracic surgery, and was a journal reviewer for the European Journal of Cardiothoracic and for the Annals of Thoracic Surgery from 2002 to 2006. (Amato C.V. 4-6.) Dr. Amato has written several articles for peer-reviewed medical journals and chapters for medical texts in cardiothoracic surgery, including a chapter on "Staged Reconstruction for Hypoplastic Left Heart Syndrome: Cavopulmonary Anastomosis." (Amato C.V. 18.) Although Dr. Amato stopped performing surgery in 2002, he has over thirty years of surgical practice, and continues to serve as a Senior Attending in Pediatric Cardiothoracic Surgery at Rush-Presbyterian. The Court finds that Dr. Amato's formal qualifications are unassailable.

As for Dr. Amato's substantive qualifications, the "liberal policy of admissibility" continues to apply. Pineda, 520 F.3d at 244. Dr. Amato need not be "the best qualified" expert, nor need he "have the specialization that the court considers must appropriate." Holbrook v. Lykes Bros. S.S. Co., 80 F.3d 777, 782 (3d Cir. 1996); see also id. at 782, 782 n. 11 (collecting cases in which an expert need not have a background in a particular specialty in order to be qualified to testify). The Court finds that Dr. Amato is more qualified than Dr. Hannan, the plaintiffs' expert in Daddio v. A.I. DuPont Hosp. for Children of the Nemours Found., 650 F. Supp. 2d 387 (E.D. Pa. 2009), whose testimony Judge McLaughlin precluded under Rule 702.

Daddio involved similar medical negligence claims that were brought against Dr. Norwood. Dr. Hannan “does not perform hemi-Fontan procedures; nor did he perform such procedures during the relevant time period.” Id. at 406. Unlike Dr. Hannan, Dr. Amato has performed a few hemi-Fontans and has written at least one chapter in a medical text on the procedure. (Amato C.V. 18.) As the Court will detail in its discussion of the reliability and fit of Dr. Amato’s opinions, his opinions are supported by medical literature; thus, the Court cannot conclude that his opinions, like those of Dr. Hannan, are based solely on “[s]ubjective belief and unsupported speculation.” Daddio, 650 F. Supp. at 409.

Dr. Amato’s qualifications are also distinguishable from those of the plaintiff’s expert in Peters v. Gelb, 314 A.2d 901 (Del. 1974), which Defendants rely upon for the proposition that a surgeon who stopped performing the surgical procedure at issue years before the surgery that is the subject of litigation took place, lacks the qualifications to testify. (Madden Qualifications Mot. 5; Papacoda Qualifications Mot. 7.) In Peters, the plaintiffs’ expert had not performed a vasectomy since 1964, six years before the surgery at issue in the case. 314 A.2d at 903. The Peters Court, however, did not disqualify the plaintiffs’ expert based solely on the time gap between his last surgery and the surgeries at issue, but did so because he lacked “some current expertise in [the] developing art, either through study of texts or medical journals or through practical experience.” Id. “[L]est [its] holding be read too broadly, [the Peters Court] emphasize[d] that each case must be carefully judged by its particular facts and circumstances.” Id. Dr. Amato not only possesses some experience in performing hemi-Fontan procedures; he has also written articles and chapters on the relevant subject matter, and as the sources he attached to support his opinions indicate, has extensively reviewed medical texts and journals

respecting the procedure. In addition, these cases involve a much shorter temporal proximity between Dr. Amato ceasing to perform surgeries and the surgeries in question—a span of one to two years, at most—than the six year gap in Peters. Accordingly, the Court concludes that Peters is inapposite and, in light of Rule 702’s “liberal policy of admissibility,” Pineda, 520 F.3d at 244, that Dr. Amato is qualified to testify as an expert at trial.

**b. Reliability and Fit**

This Court “acts as a gatekeeper to ensure that any and all expert testimony or evidence is not only relevant, but also reliable.” Pineda, 520 F.3d at 243 (internal quotation marks omitted). Pursuant to Rule 702’s second requirement, “an expert’s testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable.” In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 (3d Cir. 1994). The Third Circuit, however, has “cautioned that the evidentiary requirement of reliability is lower than the merits standard of correctness,” Pineda, 520 F.3d at 247 (internal quotation marks and alterations omitted), because “[a]dmissibility decisions focus on the expert’s methods and reasoning,” while “credibility decisions arise after admissibility has been determined.” Kannankeril v. Terminix Int’l, Inc., 127 F.3d 802, 806 (3d Cir. 1997).

Several non-exhaustive factors guide the Court’s inquiry into the reliability of expert testimony:

(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique’s operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

Pineda, 520 F.3d at 247-48. These factors are “neither exhaustive nor applicable in every case,”

Kannankeril, 127 F.3d at 806-07, because the inquiry into the reliability of expert testimony is meant to be “flexible,” Daubert, 509 U.S. at 594. The Court, however, remains mindful that “[t]he Rules of Evidence embody a strong preference for admitting any evidence that may assist the trier of fact.” Id. at 243.

In the present cases, the Court finds that Dr. Amato’s opinions are reliable, such that their credibility should be left up to the jury to evaluate. As this Memorandum has already detailed, Dr. Amato possesses both the formal and substantive qualifications to testify as an expert about Kaitlyn and Mykenzie’s open-heart surgeries. As for the remaining non-exhaustive factors, the Court finds that Dr. Amato’s opinions are supported by medical literature. For example, in support of his opinion that Kaitlyn and Mykenzie’s surgeries “clearly required that cooling extend for 15-20 minutes in order to best protect the baby’s vital organs, especially the brain,” and that the DuPont surgeons were negligent in only cooling Kaitlyn and Mykenzie for ten minutes (Amato Madden Rep. 3), Dr. Amato cited a cardiac surgery textbook that states that for cardiopulmonary bypass, although “small infants can sometimes decrease to 18° C within 10 minutes,” “rapid cooling has been demonstrated to be suboptimal for circulatory arrest. . . . Therefore, the cooling period should last at least 20 minutes and may at times approach 30 minutes.” Nicholas T. Kouchoukos, M.D., et al., Cardiac Surgery: Morphology, Diagnostic Criteria, Natural History, Techniques, Results, and Indications 117 (3d ed. Kirklin/Barrett-Boyes 2003). The same text supports Dr. Amato’s conclusion that a prolonged circulatory arrest period can cause damage, stating that “arrest times of longer than 60 minutes . . . may be associated with impairment of intellectual function and development, and some of the data suggest that arrest periods of longer than 45 minutes may not be entirely safe.” Id. at 77-78.

As for Dr. Amato's opinion that Mykenzie's left superior vena cava should not have been ligated, another cardiac surgery text provides that in conducting a hypothermic cardiopulmonary bypass, a left superior vena cava, should only be ligated "when small or if connected to a reasonably sized right superior vena cava via a left innominate vein. Otherwise it should be cannulated directly . . . ." Eduardo Arcinegas, M.D., Pediatric Cardiac Surgery 345 (Year Book Med. 1985). In light of these sources, Dr. Amato's conclusions cannot be said to be unsupported by medical research and literature, and therefore, not generally accepted within the medical community. This case, therefore, stands in contrast from Daddio and Reger v. The A.I. DuPont Hospital for Children of the Nemours Foundation, 259 F.App'x 499, 500 (3d Cir. 2008), in which the expert, Dr. Hannan, who had never performed a hemi-Fontan, provided no "specific scientific articles, textbooks, or studies to support his conclusions." Daddio, 650 F. Supp. at 410; see also Reger, 259 F. App'x at 500 (finding that Dr. Hannan's opinion "was not supported by citation or reference to any scientific data or texts").

Given the liberal thrust of the Federal Rules of Evidence, the flexible nature of the Daubert inquiry, the proper roles of the judge and the jury in evaluating an expert's credibility, and the medical literature buttressing Dr. Amato's conclusions, the Court finds his opinions to be sufficiently reliable for Rule 702 purposes.

As for the final requirement of fit, the "same standard of reliability extends to th[is] step in the expert's analysis." In re Paoli, 35 F.3d at 745. As the Supreme Court explained in Daubert, "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." 509 U.S. at 591-92. Dr. Amato's deposition testimony and report indicate that he reviewed Kaitlyn and Mykenzie's medical records in depth and drew

his conclusions based on the facts in the record. Defendants' contention that Dr. Amato did not explain why other factors did not in fact cause Kaitlyn and Mykenzie's deaths (Madden Reliability & Fit Mem. 4, 10; Papacoda Reliability & Fit Mem. 8, 11), goes to the weight and sufficiency of Dr. Amato's evidence, considerations appropriate to the jury's ultimate evaluation of his credibility. In light of Rule 702's presumption of admissibility, the Court concludes that Dr. Amato meets the fit requirement. Accordingly, Dr. Amato has satisfied all three of Rule 702's requirements, and his trial testimony will not be precluded.

## **V. Motions for Summary Judgment**

### **A. Legal Standard**

Summary judgment is appropriate "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). An issue is "genuine" if the evidence is such that a reasonable jury could return a verdict for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A factual dispute is "material" if it might affect the outcome of the case under governing law. Id.

A party seeking summary judgment always bears the initial responsibility for informing the district court of the basis for its motion and identifying those portions of the record that it believes demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). Where the non-moving party bears the burden of proof on a particular issue at trial, the moving party's initial burden can be met simply by "pointing out to the district court that there is an absence of evidence to support the non-moving party's case." Id. at 325. After the moving party has met its initial burden, the adverse party's response must, "by

affidavits or as otherwise provided in this rule [ ] set out specific facts showing a genuine issue for trial.” Fed. R. Civ. P. 56(e). Summary judgment is appropriate if the non-moving party fails to rebut by making a factual showing “sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” Celotex, 477 U.S. at 322. Under Rule 56, the Court must view the evidence presented on the motion in the light most favorable to the opposing party. Anderson, 477 U.S. at 255.

## **B. Discussion**

### **1. The Parties’ Contentions**

Defendants seek summary judgment on two bases: Plaintiffs’ failure to establish “but for” causation for Kaitlyn and Mykenzie’s injuries through Dr. Amato’s testimony; and Plaintiffs’ inability to demonstrate the requisite elements of informed consent. The Court addresses each in turn.

#### **a. “But for” Causation**

In their Motions to preclude Dr. Amato’s testimony on the basis of unreliability and lack of fit to the facts of the pending cases, Defendants seek summary judgment relief dismissing all negligence and informed consent claims against them. Defendants aver that Dr. Amato’s “unscientific, inexact, and prejudicial analysis” fails to meet Delaware law’s “rigorous” requirement that plaintiffs in medical negligence cases establish “but for” causation. (Madden Reliability & Fit Mem. 34; Papacoda Reliability & Fit Mem. 24, 33.) Specifically, Defendants fault Dr. Amato for not identifying specific factors causing Kaitlyn and Mykenzie’s injuries and explaining why other factors independent of Dr. Norwood’s surgical procedures were not the causes of death. (Madden Reliability & Fit Mem. 18-21; Papacoda Reliability & Fit Mem. 20-



25.) Defendants conclude that Dr. Amato’s “conclusory testimony” fails to establish causation, as required by Delaware medical malpractice law, and thus, that they are entitled to summary judgment on all claims. (Papacoda Reliability & Fit Mem. 31; see also Madden Reliability & Fit Mem. 34-35.)

With respect to proving causation, Plaintiffs respond that Delaware law, despite requiring a showing of “but for” causation, “has long recognized that there may be more than one proximate cause of an injury,” and “does not require medical experts to couch their opinions in legal terms” or to use any “magic words.” (Resp. to Madden Reliability & Fit Mem. 28-29; Resp. to Papacoda Reliability & Fit Mem. 21.) Plaintiffs further aver that “Dr. Amato more than adequately set forth . . . his view of the violations of the standard of care in this case” and how these violations resulted in Kaitlyn and Mykenzie’s deaths. (Resp. to Madden Reliability & Fit Mem. 29; Resp. to Papacoda Reliability & Fit Mem. 21.) Plaintiffs thereby conclude that taken “as a whole,” Dr. Amato’s testimony provides a sufficient basis for determining the “but for” cause of Kaitlyn and Mykenzie’s deaths, and thus, that the Court should not grant summary judgment in Defendants’ favor. (Resp. to Madden Reliability & Fit Mem. 29-30; Resp. to Papacoda Reliability & Fit Mem. 22.)

#### **b. Informed Consent**

Defendants have also moved for partial summary judgment on the informed consent claims because Plaintiffs’ “own testimony shows that they were well informed about the risks associated with [the] surgeries and gave informed consent to the procedures” Kaitlyn and Mykenzie] underwent. (Papacoda Partial Summ. J. Mot. 3; see also Madden Partial Summ. J. Mot. 3-5) Defendants contend that in both cases, Plaintiffs recall being told that the procedures

posed a risk of death, that the third stage might be completed by catheterization, and that the first two surgeries might be modified in order for Kaitlyn and Mykenzie to be candidates for the Catheterization Fontan. (Madden Partial Summ. J. Mot. 3-5; Papacoda Partial Summ. J. Mot. 4-5). Defendants also aver that Dr. Amato “could not describe what information is ‘customarily given’ to parents of infants undergoing a hemi-Fontan” and “believes that there is no custom or uniform practice followed by surgeons for this discussion.” (Madden Partial Summ. J. Mot. 4; Papacoda Partial Summ. J. Mot. 6.) Defendants argue that Plaintiffs thereby failed to demonstrate what information is customarily given to patients undergoing the same procedure. (Madden Partial Summ. J. Mot. 9; Papacoda Partial Summ. J. Mot. 11.)

In response, Plaintiffs assert that “[t]here are ample questions on the record—questions only the jury can resolve—as to whether or not Plaintiffs were ever informed of the risks associated with the procedure[s]” Kaitlyn and Mykenzie received. (Resp. to Papacoda Partial Summ. J. Mot. 1; see also Resp. to Madden Partial Summ. J. Mot. 1) In particular, Plaintiffs contend that they were only informed of the “bare essentials of the surgeries,” and were never told that “the surgery was experimental and implemented a stent that was not approved by the FDA.” (Resp. to Papacoda Partial Summ. J. Mot. 5; see also Resp. to Madden Partial Summ. J. Mot. 3-4) Plaintiffs also argue that they were not informed about the surgery’s “commonly encountered risks” or “alternatives to the hemi-Fontan procedure, including the bidirectional Glenn.” (Resp. to Madden Partial Summ. J. Mot. 6; Resp. to Papacoda Partial Summ. J. Mot. 6.) As support, Plaintiffs attach affidavits from Madden and Mrs. Papacoda detailing the benefits and risks of, and alternatives to, the hemi-Fontan that Defendants purportedly failed to disclose. (Resp. to Madden Partial Summ. J. Mot., Ex. B; Resp. to Papacoda Partial Summ. J. Mot., Ex.

B.) As for causation, Plaintiffs aver that they may show this by demonstrating that had they been properly informed, they would have made a different decision about the surgeries that Kaitlyn and Mykenzie underwent. (Resp. to Madden Partial Summ. J. Mot. 11; Resp. to Papacoda Partial Summ. J. Mot. 12.) Plaintiffs conclude that “[t]he record on these issues is sufficient to deny summary judgment.” (Resp. to Papacoda Partial Summ. J. Mot. 12; see also Resp. to Madden Partial Summ. J. Mot. 11)

Defendants reply that Madden and Mrs. Papacoda’s affidavits “should be stricken as . . . ‘sham affidavit[s]’ as a party may not submit an affidavit changing her testimony in response to a summary judgment motion.” (Madden Partial Summ. J. Reply 1; Papacoda Partial Summ J. Reply 1.) In particular, Defendants contend that Madden’s affidavit contradicted her testimony that she “was aware that there would be potential modifications to the second surgery so Mykenzie could have a third noninvasive surgery.” (Madden Partial Summ. J. Reply 3.) In a subsequent letter to the Court, Defendants explained that Madden’s affidavit stated that “[p]rior to Mykenzie’s second surgery, the hemi-Fontan, neither Dr. Norwood nor Dr. Pizarro discussed the surgery with me,” or “[w]hat the procedure involved” (Madden Aff. ¶¶ 8, 11a). Letter from Sarah Lynn Petrosky, Defendants’ Counsel, to Judge Michael M. Baylson 2 (Dec. 23, 2009) (on file with the Court) (hereinafter Madden Defs.’ Letter). Defendants, however, aver that this contradicts her deposition testimony that “[r]ight before [Mykenzie’s] surgery, [Dr. Pizarro] said that she would have . . . the second procedure . . . the day before surgery is when he presented to me that she would go in and that was the first time I heard that it wouldn’t have to be an invasive surgery (Madden Dep. 89:8-9, 14, 17-20). Madden Defs.’ Letter 2. In the Papacoda case, Defendants aver that Mrs. Papacoda’s affidavit stated that prior to Kaitlyn’s hemi-Fontan

surgery, neither Dr. Norwood nor Dr. Pizarro discussed the surgery and its procedure with her,<sup>2</sup> but that she previously testified at her deposition that she had been informed about the risks and benefits to the procedure,<sup>3</sup> and that she “wanted Kaitlyn’s third procedure performed by catheterization because it was less risky than open-heart surgery.” Letter from Sara Lynn Petrosky, Defendants’ Counsel, to Judge Michael M. Baylson 2 (Dec. 23, 1999) (on file with the Court) (hereinafter Madden Defs.’ Letter). Defendants therefore conclude that both Madden and Mrs. Papacoda’s affidavits should be discarded as being “shams.”

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<sup>2</sup>In particular, the relevant portions of Mrs. Papacoda’s affidavit are as follows:

10. . . . We were not told that the non-surgical third-stage procedure was experimental, that there was little known about the risks of the approach, the long term benefits or potential harms, or the needing [sic] for the treatment or surgery in the first place. . . .
11. At no time prior to Kaitlyn’s surgery on June 25, 2003, did Dr. Norwood discuss any of the following with us:
  - a. The fact that Dr. Norwood did not know the risks associated with the surgery he planned to perform on Kaitlyn . . . .

(Madden Aff., Resp. to Madden Partial Summ J., Ex. B.)

<sup>3</sup>Defendants identified the following as the key portions of Mrs. Papacoda’s deposition testimony:

Q: Did [Dr. Norwood] talk to you at all about Stage I and Stage II during your first visit with [him]?

A. Yes.

\* \* \*

I think that once the surgical procedures were done, noone really knew what the life span was going to be, but there were children out there doing very well who would need continued care and to be monitored, but that her life could be relatively normal.

\* \* \*

And the percentage, I believe that was given to us of survival was 85 percent for the first procedure. And that it increased for the second and third procedure.

(Papacoda Dep. 23, 46, & 47.)

Plaintiffs claim that closer analysis of Madden and Mrs. Papacoda's depositions and affidavits indicates that there are no contradictions and that the affidavits are not shams. Letter from Aaron J. Freiwald, Plaintiffs' Counsel, to Judge Michael M. Baylson 2 (Dec. 22, 2009) (on file with the Court) (hereinafter Pls.' Letter). Plaintiffs contend that under Third Circuit law, "[a]n affidavit must blatantly and unequivocally contradict deposition testimony in order to be considered a 'sham affidavit.'" Pls.' Letter 1. With respect to Madden, Plaintiffs aver that she only testified at her deposition that she met with a Dr. Gidding, who discussed the background, surgical procedures, and some risks respecting the surgery, but that even he did not discuss the risks and alternatives for which Madden claims lack of informed consent. Pls.' Letter 2. Plaintiffs continue that Madden testified that aside from risk of death, she was not informed of "other risks of surgery, for example, risk of infection." Pls.' Letter 3. With respect to Mrs. Papacoda's affidavit, Plaintiffs aver that Mrs. Papacoda has never claimed in either her affidavit or her deposition that she "was not informed at all about the third stage procedure being a non-surgical procedure," and that she was not informed about this procedure being "part of an experimental program" that lacked FDA approval and was untested. Pls.' Letter 5-6. Finally, Plaintiffs contend that although Mrs. Papacoda believed the third procedure to be "less than risky than open-heart surgery," she had only been "informed of the mortality rates associated with the traditional procedure, which, as it turns out, Kaitlyn did not have," which still does not indicate that she was aware of the risks of the "experimental," anticipated third-stage procedure. Pls.' Letter 6. Accordingly, Plaintiffs conclude that neither Madden nor Mrs. Papacoda's affidavits should be discarded as shams, and that summary judgment should not be awarded in Defendants' favor.

## **2. Analysis**

### **a. “But for” Causation**

As Culver v. Bennett, 588 A.2d 1094 (Del. 1991), makes clear, Delaware has a “but for” or proximate causation rule, which is defined as “that direct cause without which the accident would not have occurred.” Id. at 1097 (internal quotation marks omitted). Nonetheless, as the Culver case itself states, Plaintiffs need only show “that there is a reasonable connection between the negligent act or omission of the defendant and the injury with the plaintiff suffered.” Id. As detailed above, Dr. Amato provided medical literature indicating that insufficient cooling time, a prolonged cardiac arrest period, and in Mykenzie’s case, an improper ligation caused injury and organ damage. Based on this, Dr. Amato “reasonably concluded” that these factors were “but for” causes of Kaitlyn and Mykenzie’s deaths. Because “Delaware has long recognized that there may be more than one proximate cause of an injury,” id., Plaintiffs need not rule out all other proximate causes of Kaitlyn and Mykenzie’s deaths in order to make their proximate causation showing. Drawing all inferences in favor of Plaintiffs, the Court cannot conclude, as a matter of law, that Dr. Amato failed to demonstrate “but for” causation in the present cases. Thus, the Court will not award summary judgment on the basis of failure to establish “but for” causation.

### **b. Informed Consent**

As for whether to award partial summary judgment to Defendants on the informed consent claims, Delaware law requires Plaintiffs to demonstrate, by a preponderance of evidence and through expert testimony, that “the health care provider did not supply information regarding such treatment, procedure or surgery to the extent customarily given to patients.” 18 Del. C. § 6852(a)(2). Defendants make two arguments in support of their motions for partial summary

judgment: First, that Madden and Mrs. Papacoda's affidavits asserting that they were not informed of various risks of and alternatives to the surgeries in question are "shams" that should be discarded by the Court, and that absent such affidavits, there is no genuine issue of fact as to whether Defendants properly informed Plaintiffs; and second, that Dr. Amato failed to establish what information is customarily given to patients, and thus, that Plaintiffs cannot demonstrate a prima facie case of informed consent under Delaware law. (Madden Partial Summ J. Reply 1; Papacoda Partial Summ. J. Reply 1.) Each argument will be addressed in turn.

### **1. Sham Affidavits**

The "sham affidavit" doctrine generally "refers to the courts' practice of disregarding an offsetting affidavit that is submitted in opposition to a motion for summary judgment when the affidavit contradicts the affiant's prior deposition testimony." Baer v. Chase, 392 F.3d 609, 624 (3d Cir. 2004 (internal quotation marks omitted)). The Third Circuit has explained the rationale for the doctrine as follows:

A sham affidavit is a contradictory affidavit that indicates only that the affiant cannot maintain a consistent story or is willing to offer a statement solely for the purpose of defeating summary judgment. A sham affidavit cannot raise a genuine issue of fact because it is merely a variance from earlier deposition testimony, and therefore no reasonable jury could rely on it to find for the movant.

Jimenez v. All Am. Rathskeller, 503 F.3d 247, 253 (3d Cir. 2007). The Third Circuit, however, has adopted a "flexible approach" to the doctrine, observing that "not all contradictory affidavits are necessarily shams." Id. For example, "an affiant has the opportunity to offer a satisfactory explanation for the conflict between the prior deposition and the affidavit," such as by presenting "corroborating evidence [that] establish[es] that the affiant was understandably mistaken, confused, or not in possession of all the facts during the previous deposition." Id. (internal

quotation marks omitted).

The Court begins by examining whether Madden and Mrs. Papacoda's affidavits conflict with their earlier deposition testimony. Madden's affidavit states that neither Dr. Norwood nor Dr. Pizarro "discussed" the hemi-Fontan surgery and procedure with her. (Madden Aff. ¶¶ 8 11a). At her deposition, Madden testified that aside from receiving background on the mortality rate and general procedure associated with the surgery from another doctor, she in fact spoke briefly with Dr. Pizarro about the surgery "[r]ight before [Mykenzie's second] surgery," which was "the first time [she] heard that it wouldn't have to be an invasive surgery." (Madden Dep. 90:8, 19-20.) Madden avers that there is a distinction between mentioning a feature of a surgery and discussing the details of the surgery, which Madden contends that Dr. Pizarro never did. See Letter from Aaron J. Freiwald, Plaintiffs' Counsel, to Judge Michael M. Baylson 2-3 (on file with the Court) (hereinafter Pls.' 2d Letter). The Court finds it significant that the rest of Madden's affidavit lists specific risks or alternatives that Dr. Pizarro purportedly did not disclose, for example, the fact that Deep Hypothermic Circulatory Arrest was being used for the hemi-Fontan, or that there was a "surgical alternative . . . known as the bidirectional Glenn." (Madden Aff. ¶ 11b-e.) Moreover, the fact that Madden draws a distinction between "discussions," understood to be lengthier and more substantive, and "talks" is confirmed by an earlier portion of her affidavit which states that "Dr. Pizarro did not discuss what the surgery entailed or the procedure carried. Dr. Pizarro simply told me that I needed to sign the consent form" for the first surgery. (Madden Aff. ¶ 7.) The Court, therefore, is not persuaded that the affidavit rises to the level of a "sham" demonstrating that Madden "cannot maintain a consistent story or is willing to offer a statement solely for the purpose of defeating summary judgment,"



when the rest of her affidavit does not even arguably contradict her prior deposition testimony. See Davis v. Mothers Work, Inc., No. 04-3943, 2005 WL 1863211, at \*7 n.16 (E.D. Pa. Aug. 4, 2005) (Yohn, J.) (refraining from applying the “sham affidavit” doctrine because the witness’s “declaration is not truly inconsistent with her prior deposition testimony”). Accordingly, the Court will not reject or ignore Madden’s affidavit.

As for Mrs. Papacoda’s affidavit, Defendants take issue with her statement that she was not informed of the surgical procedure’s “long-term benefits or potential harms, or the needing [sic] for the treatment or surgery in the first place,” or the fact that “the risks associated with the surgery” were unknown (Papacoda Aff. ¶¶ 10-11a). Defendants contend that this statement is at odds with portions of her deposition testimony in which she concedes that Dr. Norwood spoke with her about the first two surgical procedures, that she was informed of that there was a risk of mortality, and that she knew that nobody knew the life span of children who have completed the surgical procedures. (Defs. Papacoda Letter 2; Papacoda Dep. 23, 46-47.) Defendants, however, have mischaracterized Mrs. Papacoda’s affidavit statements. Mrs. Papacoda did not state that she was not told of any benefits or harms relating to the overall surgery; rather, the sentences in question focus on how Dr. Norwood did not inform her and her husband as to the risks of the “non-surgical third-stage procedure” that would be performed after he “modified the hemi-Fontan for Kaitlyn by inserting a metal stent.” (Papacoda Aff. ¶ 10). Unlike her deposition testimony, which relayed a couple of general risks she knew were associated with the overall procedure, her affidavit focuses on the risks associated with the modified hemi-Fontan and non-invasive third surgical procedure. The Court, therefore, sees no conflict between the two statements and will not strike her affidavit as a “sham,” and will not grant summary judgment on

the basis that the affidavits themselves do not create a genuine issue of material fact. The Court now turns to the remaining question of whether Plaintiffs has met their burden of demonstrating a prima facie case of lack of informed consent under Delaware law.

## **2. “Customarily Given” Information**

An expert cannot meet the requirement under Delaware medical malpractice law that “the health care provider did not supply information . . . to the extent customarily given to patients,” 18 Del. C. § 6852(a)(2), merely by testifying that the physicians “‘should have’ provided more information” to the patients. Duryea v. Perrota, No. 97C-08-055, 1999 WL 1427769, at \*2 (Del. Super. Ct. Oct. 27, 1999); see also Good v. Bautista, 1987 WL 12439, at \*2 (Del. Super. Ct. Ct. Jun. 8, 1987) (finding that Plaintiff’s expert failed to sustain the burden of proof because he would not opine as to customarily given information, but “would simply testify that in his opinion more information should have been given to Plaintiff”).

Duryea, however, involved an expert who “stop[ped] well short of expressing an opinion that the failure to supply [additional] information [wa]s a breach of the standard of care or is information customarily given to patients before this type of procedure.” 1999 WL 1427769, at \*2. Good, meanwhile, did not preclude the expert’s testimony based upon his inability to sustain the plaintiff’s burden of proof as to informed consent; rather, the Delaware Superior Court found the expert unqualified, having no experience or awareness respecting the surgical procedure at issue. 1987 WL 12439, at \*1.

Unlike Duryea and Good, the present cases involve expert reports which fail to use the magic words of “information . . . customarily given to patients” undergoing the procedures at issue, 18 Del. C. § 6852(a)(2), but unquestionably opined that Plaintiffs were not properly

informed as to the risks of, and alternatives to, the surgical procedures employed. In his reports, Dr. Amato stated that the responsible surgeons “did not discuss any aspect” of deep hypothermic circulatory arrest, “the risks associated with bypass, deep cooling or circulatory arrest,” or the reasonable alternative to the hemi-Fontan procedure with Plaintiffs. (Amato Papacoda Rep. 3; see also Amato Madden Rep. 5.) Then, at his deposition in the Madden case, Dr. Amato clarified that he believed that “any other surgeon who is knowledgeable about circulatory arrest and realizing the consequences that could occur [would] definitely have to state to parents that there can be a period of circulatory arrest that would lead to brain damage, [such that] a period of circulatory arrest . . . might influence the child’s survival.” (Amato Madden Dep. 195:2-11.) Dr. Amato continued that a surgeon should “explain the alternatives of circulatory arrest,” inform parents of the circumstances requiring circulatory arrest, “either excessive bleeding [or] undefined anatomy,” and “tell them the sequences, the effects,” and benefits of the procedure. (Amato Madden Dep. 196:14-15, 200:6-7, 200:20-21.)

Notwithstanding Duryea and Good, the Delaware Supreme Court disapproved of “erroneously requir[ing] an expert to articulate certain ‘magic words,’” which has the effect of “exalt[ing] form over substance.” Barriocanal v. Gibbs, 697 A.2d 1169, 1172 (Del. 1997). The Barriocanal Court held that it was reversible error for the trial court to exclude expert evidence, stating that “the trial court should have evaluated the substance of the proffered testimony as a whole to determine if it was sufficiently reliable to present to the jury. The jury’s role then would be to evaluate the weight of the testimony.” Id. at 1172-73. In light of Barriocanal, Dr. Amato’s detailed opinions as to the information that Plaintiffs ordinarily would have been informed about, but were not in fact told, suffices to preclude summary judgment relief on the

informed consent claims. Accordingly, an issue of genuine material fact exists over whether Defendants failed to supply Plaintiffs with information customarily given to patients undergoing hemi-Fontan procedures, and Defendants have failed to show any basis for granting summary judgment or partial summary judgment in their favor.

## **V. Conclusion**

For the reasons detailed above, Defendants' Motions will be denied. Appropriate Orders follow.

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